

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed January 19, 2010. Claims 1, 2, 5-8, 15-17, 21-23, and 26-32 were pending and rejected in view of cited art.<sup>1</sup> Claims 1, 15, and 23 are amended. Claims 1, 2, 5-8, 15-17, 21-23, and 26-32 remain pending in view of the above amendments, with claims 1, 15, and 23 being independent.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. PRIOR ART REJECTIONS**

#### **I. REJECTION UNDER 35 U.S.C. § 103**

The Office Action rejected claims 1, 2, 5-7, 15-17, 21-23, 28, 29, and 31 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,071,305 (*Brown*) in view of European Patent No. EP0105460 (*Tower*) per U.S. Patent No. 5,836,966 (*St. Germain*). Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown* in view of *Tower* per *St. Germain* as applied to claim 1, and further in view of U.S. Publication No. 2002/0038146 (*Harry*). Claims 26 and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown* in view of *Tower* per *St. Germain* as applied to claim 1, and further in view of U.S. Patent No. 6,758,859 (*Dang*).

As presented herein for reconsideration, (see independent claim 1, as exemplary), Applicants' claimed invention of independent claim 1 comprises an implantable device for delivering a therapeutic agent into a vessel. The stent has a plurality of circumferential rings

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<sup>1</sup> Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

each having a plurality of upper peaks and lower peaks, with the lower peaks of one circumferential ring being coupled to the upper peaks of an adjacent circumferential ring. Each of the defined circumferential rings includes a separate tubular member having a plugged proximal end connected to a plugged distal end to form the circumferential ring and a longitudinal hollow core section extending along a longitudinal axis of the tubular member from the plugged proximal end to the plugged distal end.

A multiplicity of pores are included in the tubular members that provide fluid communication between the hollow core section and the external environment. More specifically, the multiplicity of pores provide communication to the therapeutic agent contained in the hollow core section. The therapeutic agent is configured to be eluted from the hollow core sections into the vessel through the multiplicity of pores after implantation of the stent within the vessel.<sup>2</sup>

Applicants respectfully submit that the independent claims as presented for reconsideration are not anticipated nor made obvious by *Brown* either singly or in combination with any other reference of record.<sup>3</sup> In particular, *Brown* discloses a directional drug delivery stent and method of use (Title). One stent of *Brown* “is formed from an elongated or tubular member 12” and can be “in the shape of a coil or helix” (col. 5, ll. 38 and 40-41 and FIG. 1). “[E]xtending along the entire length of the elongated member” of the stent of FIG. 1 is “a concave groove” from which a drug can diffuse either directly or optionally “through [a] membrane to the desired predetermined location” (col. 5, ll. 50-52 and col. 9, ll. 14-15). As shown in FIG. 1, the proximal and distal ends of the concave groove do not appear to include any structures to plug or close them and Applicant has been unable to find any teaching or suggestion regarding the proximal and distal ends of the elongate concave groove. In addition, *Brown* neither teaches nor suggests that the proximal and distal ends of the elongate or tubular member are connected together to form the circumferential ring.

Furthermore, none of the other stents described in *Brown*, some of which include a number of optional “openings or holes”, such as within the configuration of FIG. 6, or “perforations, slits, or slots” from which the active agent may diffuse, teach or suggest the

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<sup>2</sup> The other two independent claims (e.g. claims 15 and 23) are method claims containing similar description of the implantable device.

<sup>3</sup> Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

inclusion of any structures to plug or close those openings, holes, perforations, slits, or slots. Nor does *Brown* teach or suggest that those openings, holes, perforations, slits, or slots are connected together to form the circumferential ring.

As such, Applicant respectfully submits that *Brown* fails to teach or suggest that the tubular member includes "a plugged proximal end connected to a plugged distal end to form the circumferential ring" as recited in independent claims 1, 15, and 23. Accordingly, for at least the reasons noted, independent claims 1, 15, and 23 and the claims depending therefrom<sup>4</sup> are neither anticipated nor made obvious by *Brown*, either singly or in combination with any other prior art of record<sup>5</sup>, and thus reconsideration and withdrawal of the rejection is respectfully requested.

### C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

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<sup>4</sup> Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicant thus does not acquiesce in any asserted rejections of the dependent claims.

<sup>5</sup> *Tower*, *St. Germain*, *Harry*, and *Dang* were cited as secondary references. *Tower* was cited for at least the proposition that it discloses "a stent where individual circumferential rings 21 are coupled together at welds 40, where a lower peak of a ring is coupled to the upper peak of an adjacent ring" (Office Action, p. 3). *St. Germain* was cited for the proposition that it discloses "that various stent designs are interchangeable depending on the vessel requirements . . . and can include circumferential rings with peaks and valleys linked or coupled together" *Id.* *Harry* was cited for the proposition that it discloses that "pores vary in size or shape with respect to one another . . . [and] on the stent", while *Dang* was cited for at least the proposition that it discloses that "one ring can have a first therapeutic agent and second ring can have a second therapeutic agent" (Office Action, pp. 4 and 5). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over *Brown*. For instance, although *Harry* refers to "plugs" of medicine" such plugs are not connected together to form a circumferential ring (see independent claims 1 and 15) or close an elongate tubular member, while being connected together to form a circumferential ring (see independent claim 23). Thus, even assuming *arguendo* that any of the references to *Tower*, *St. Germain*, *Harry*, and *Dang* are properly combinable with *Brown*, such combinations are clearly distinguished by the claims for the reasons already noted in reference to *Brown*.

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For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 19<sup>th</sup> day of April, 2010.

Respectfully submitted,

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